The Human Health Criteria Formula

Presentation #2: Risk, Exposure, and Uncertainty in the HHC Formula

How are HHC derived?

- The HHC formula determines the degree of risk
  - Risk = Toxicity * Exposure * Uncertainty

-Science provides us with basic information
-Policy tells us how to apply that information
-Risk Management is a matter of publicly weighing options and making a decision

Frankly- Deriving a HHC is fairly straight forward as it is all about math. What is challenging are determining what VALUES you should use for the formula. Decisions on the "appropriate" values are driven by science, science policy, and risk management decisions.

A science question is asking how much fish people eat
A policy question is asking effects from eating fish concern us?
A risk management question is what percentage of the population do we want to protect from these effects?

HHC Formula- Non Carcinogens

RfD: Reference Dose (mg/Kg-day)

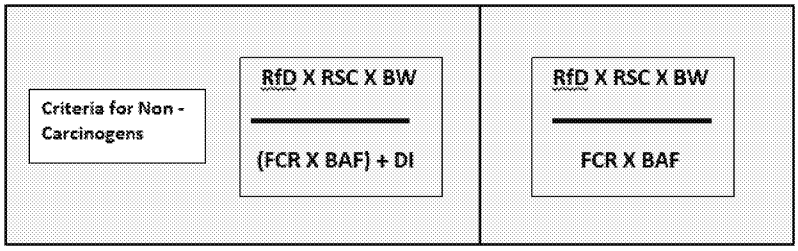
RSC: Relative Source Contribution

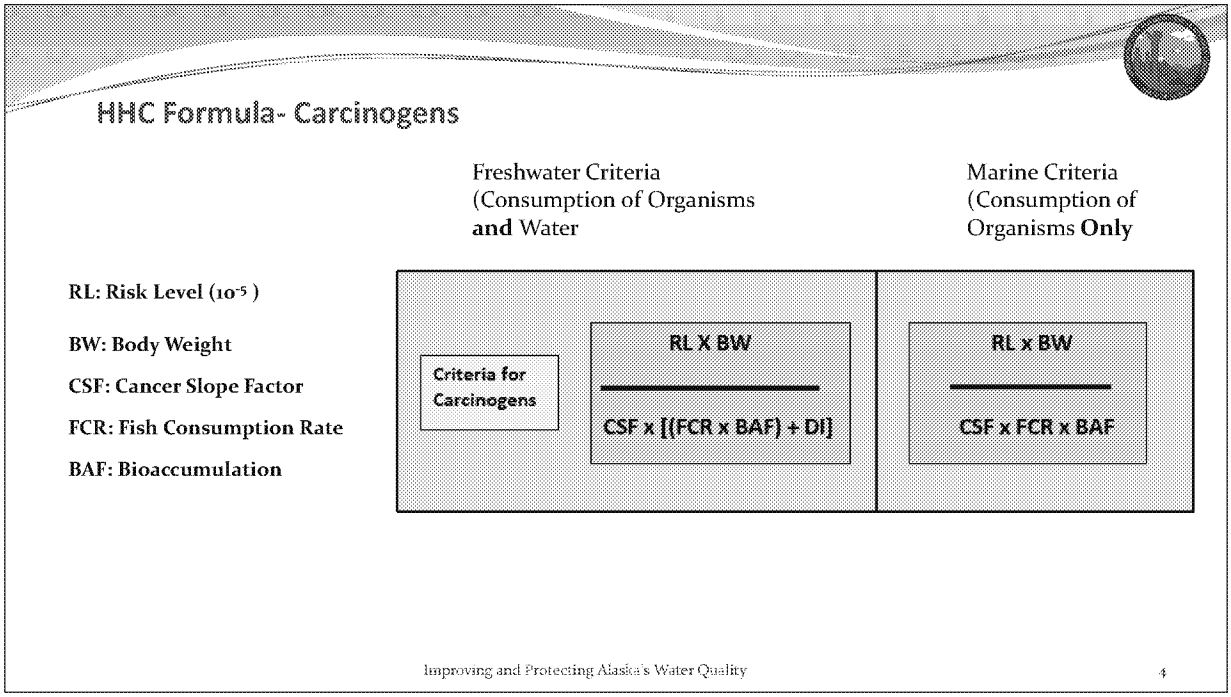
BW: Body Weight

FCR: Fish Consumption Rate

BAF: Bioaccumulation

DI: Drinking Water





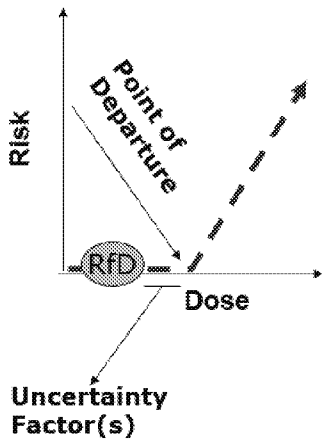
Risk Level describes the number of additional cases of cancer to a population

Cancer Slope Factor describes the 95% confidence limit of the dose to response relationship between exposure to a pollutant and risk of having a carcinogenic effect from lifetime exposure. Is often referred to as the "potency factor" as a steeper slope indicates greater risk.

The Cancer Slope Factor is used to derive the Risk Specific Dose (RSD)(mg/kg-day)
The formula used to calculate the RSD for a chemical based on 1:10,000 extra risk (10-5) is RSD = 0.00001/CSF

Toxicity: Reference Dose (NonCancer) / Cancer Slope Factor

- RfD/CSF is a toxicity value derived by EPA and published in the IRIS catalogue.
  - **Uncertainty is accounted for in the RfD.**
  - Typically has a safety factor of 10-1000 is built into the value to account for intra-species and differences between animals and humans.



Describes the acceptable daily intake of a pollutant that will not cause an affect over the course of an individual's lifetime.
Exposure with RfD is expressed as a HAZARD QUOTIENT (HQ)

HQ= daily dose/RfD

RfD info general comes from IRIS or other reputable sources of chemical toxicity reference information
Thx to Oregon DEQ for the content and image

Cancer Slope Factor or Risk Specific Dose (RSD) is Target Incremental Cancer Risk/Cancer Potency Factor

Exposure

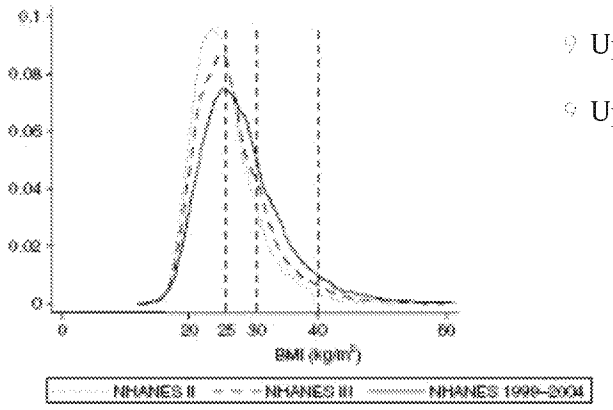
- Exposure = contact between an agent and the visible exterior of a person

  (Exposure (magnitude, frequency, duration) / Time)

- HHC Exposure Factors
  - BI= Body weight (fixed at 70 kg (80kg))
  - DI= Drinking water intake (fixed 2 liters (2.4 L))
  - FI = Fish Consumption (varies per state)
  - BAF= Bioaccumulation Factor (varies by trophic level but fixed at specific values)

Exposure simply describes those factors that a person may come in contact with. May be from natural, industrial, or domestic sources.

Body Weight



- Bodyweight is based on a fixed EPA-recommended value
- Updated 2015 = 80 kg (176 lbs)
- Update based on NHANES (1999-2006) data

BMI	Considered
Below 18.5	Underweight
18.5 to 24.9	Healthy weight
25.0 to 29.9	Overweight
30 or higher	Obese

Note that I'm going in alphabetical rather than any particular order of importance

2000 = 70 kg

EPA updated the default body weight for human health criteria to 80 kilograms based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006 (USEPA 2011). This represents the mean body weight for adults ages 21 and older. EPA's previously recommended default body weight was 70 kilograms, which was based on the mean body weight of adults from the NHANES III database (1988-1994).

According to the U.S. Center for Disease Control Alaska ranks 30th in BMI (25.58) amongst all states so there's little reason to believe that this value is not appropriate. Alaska overweight and obesity values are also fairly similar to those identified by the DHSS-Public Health (2003)

Drinking Water Intake

- Drinking Water is based on an fixed EPA-recommended value.
- 2000: 2 liters per day. Inc. all sources of water (e.g., drinking water, coffee, other beverages/food derived water)
- 2015: Settled on 2.4 liters per day. Consistent with 2011 EPA Exposure Handbook values

2014 Draft crtieria recommended 3 liters per day. This was in direct conflict with published EPA 2011 Exposure values. Value came from NHANES data collected between 2003 and 2006. Represents the 90th percentile of adults ages 21+.

Previous value was based on 86th percentile of data collected between 1994-1996-

Plenty of evidence that demonstrates that people are more aware of the importance of drinking water (liquids) and actively doing so. Little reason for AK not to adopt these values.

Fish Intake Rate/Fish Consumption Rate (FCR)

- Per EPA: States/Tribes should consider developing criteria that uses the best local data available that is representative of their target population group(s)
- Geographic/demographic differences are anticipated therefore EPA developed a preference hierarchy:
  - EPA default intake rates (22 g/d for general /142.4 g/d for subsistence)
  - Data from national surveys (NHANES or other)
  - Data reflecting similar geography/population groups (Region 10 states (175))
  - Local Data (Alaska-specific)

1992: 6.5 g/d
2000: 17.5 g/d
2015: 22 g/d

EPA values represent 90th percentile of the general U.S. population. Ages 21+

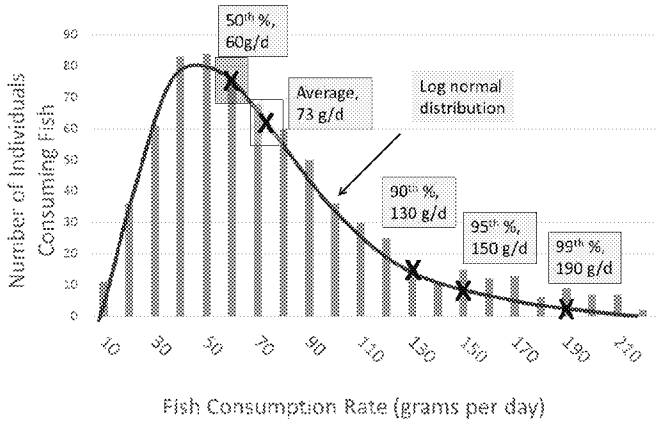
Subsistence- Been the same since 2000. EPA did not provide any additional information in 2015 regarding whether this value was still appropriate.

FCR Preference Hierarchy, Cont.

- Use of Local or Regional Data
  - Use local data for freshwater/estuarine species
  - Use of uncooked weight intake values
  - Use high-end values (90^{th} or 95^{th} percentile) **or** average values for high consuming fish population (if using mean, should base on consumers only).
- Fairly common practice for states to develop HHC values based on local data (ME, NY, MN, WI, OR, WA (Regional approach), ID (in progress))

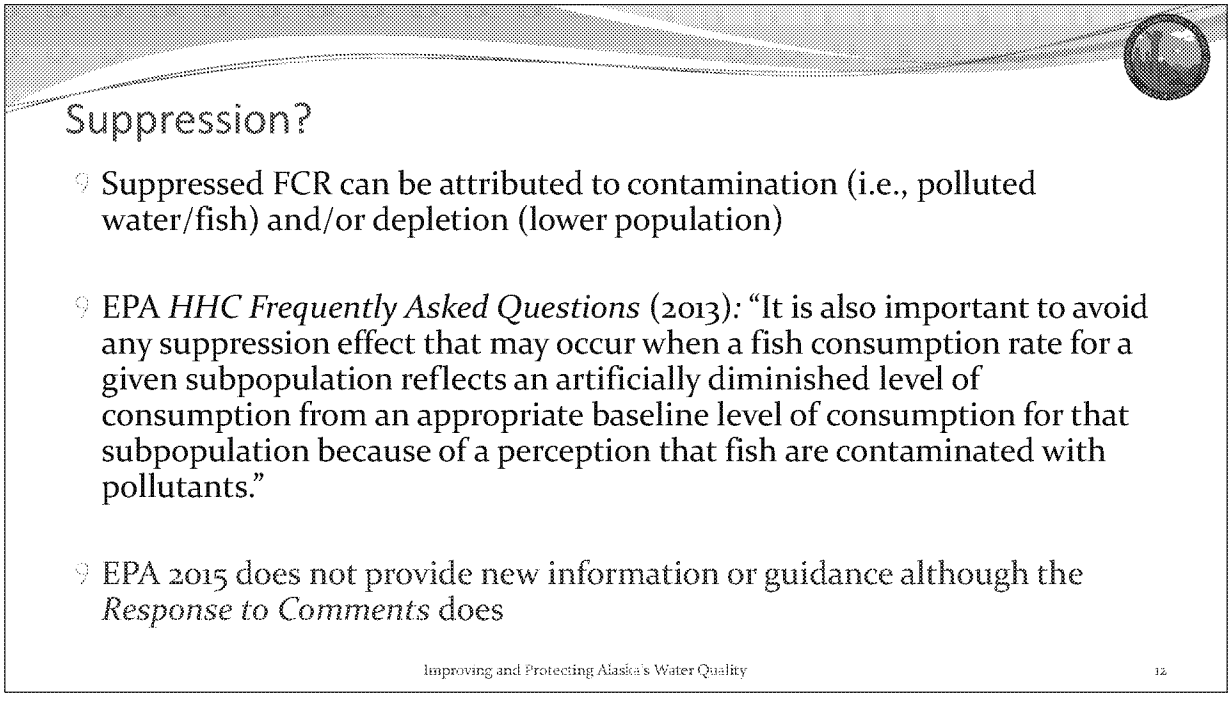
HHC: Population of interest: General or subset?

- The fish consumption rate (FCR) in the HHC should reflect the rate of consumption by the population of concern
- (Mean, 90th, 95th, 99th)



Alaska will need to make a TECHNICAL and a POLICY decision on what part of this curve they want to use for the basis of protection. Setting the value at the 99th would be very problematic (although that is how EPA got 142 g/d for the national subsistence criteria in the 2000 recommendation) because it would create a situation that may be unrealistic- Do folks really eat that much fish ALL their lives? Doesn't account for a margin of error. Setting it too low may not accurately capture the concerns of the most "at risk" population.

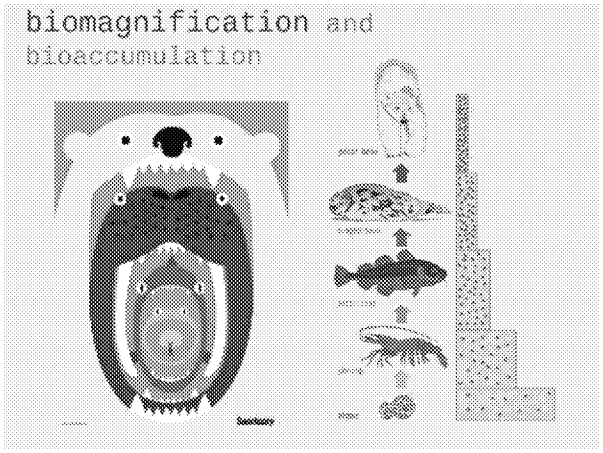
Different states have taken different approaches. EPA methodology does not prescribe a particular approach.



Essentially- what this means is that if your FCR baseline is artificially suppressed, how are you supposed to determine whether your WQC is protective? Race to the bottom argument….
DEC plans to revisit this issue with you at a future technical workgroup meeting

Suppression is multifaceted. In addition to the points you noted, factors related to suppression include:
Reduction in fish consumption from historic rates due to a variety of causes.
Fears of chemical contamination
Reduced fish populations due to loss of habitat or chemical contamination
Changes in social structure such that harvesting is reduced
Loss of access to fishing locations
Laws or regulations restricting fishing
Inadequate fishing gear
The key point regarding suppression is that we don't want to use suppressed fish consumption rates to compute ambient water quality criteria that maintain the status quo of a degraded environment. The purpose of criteria should be to restore the environment to appropriate quality and maintain it there.

Bioaccumulation Rate



- Bioaccumulation is exposure through diet, water contact, and trophic position (where in the food chain)
- BAF can range from 1- 1000's for highly bioaccumulative compounds (e.g., PCBs)
  - Low bioaccumulation = exposure from drinking water
  - High bioaccumulation = exposure from eating fish

EPA currently recommends adoption of a BAF based on trophic level (2-4)

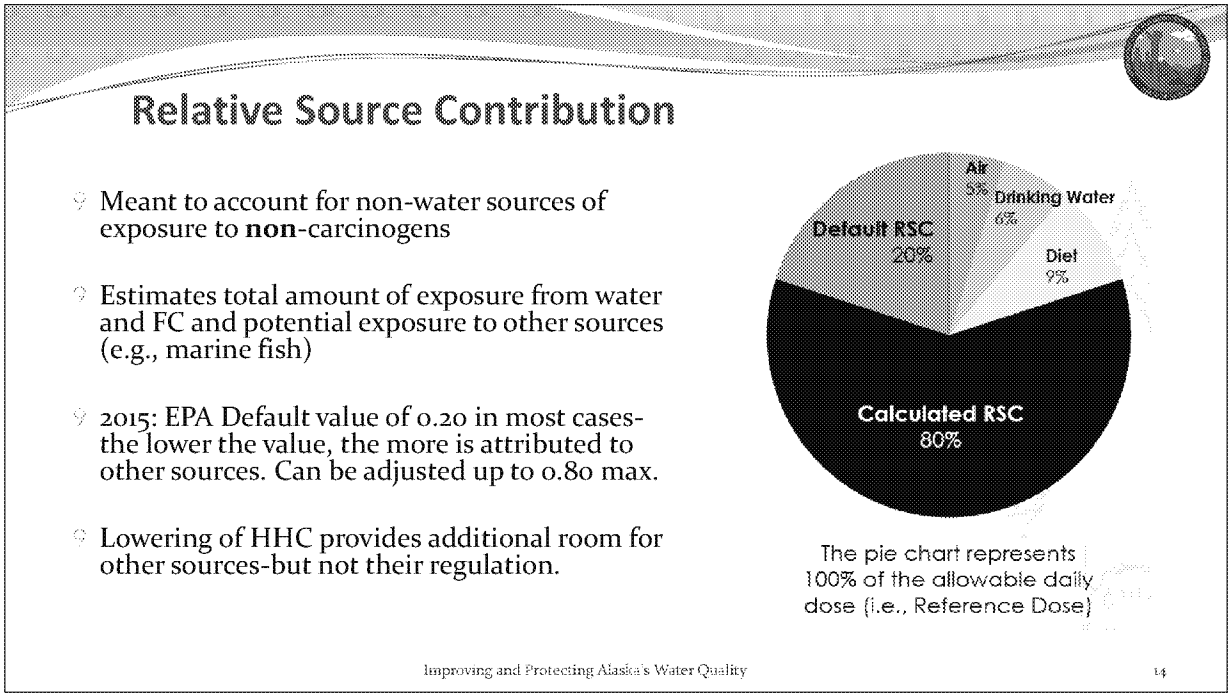
Bioconcentration refers to the uptake and retention of a chemical by an aquatic organism from water only while bioaccumulation considers all surrounding media (water, food, sediment)

Use of bioaccumulation rates were recommended in 2000 but have been rarely used due to complications with having the "right" kind of data to include in the model-fairly site-specific in nature unless you have a large data set.

Bioconcentration data is easier since it simply involves putting a fish in sample water in a lab.

Bioaccumulation is a function of the bioavailability of contaminants in combination with species-specific uptake, concentration of contaminates over time, and elimination processes. Toxicity is determined by the exposure of an animal to bioavailable contaminants in concert with the animal's sensitivity to the contaminant. Increase in concentration of a pollutant in an organism

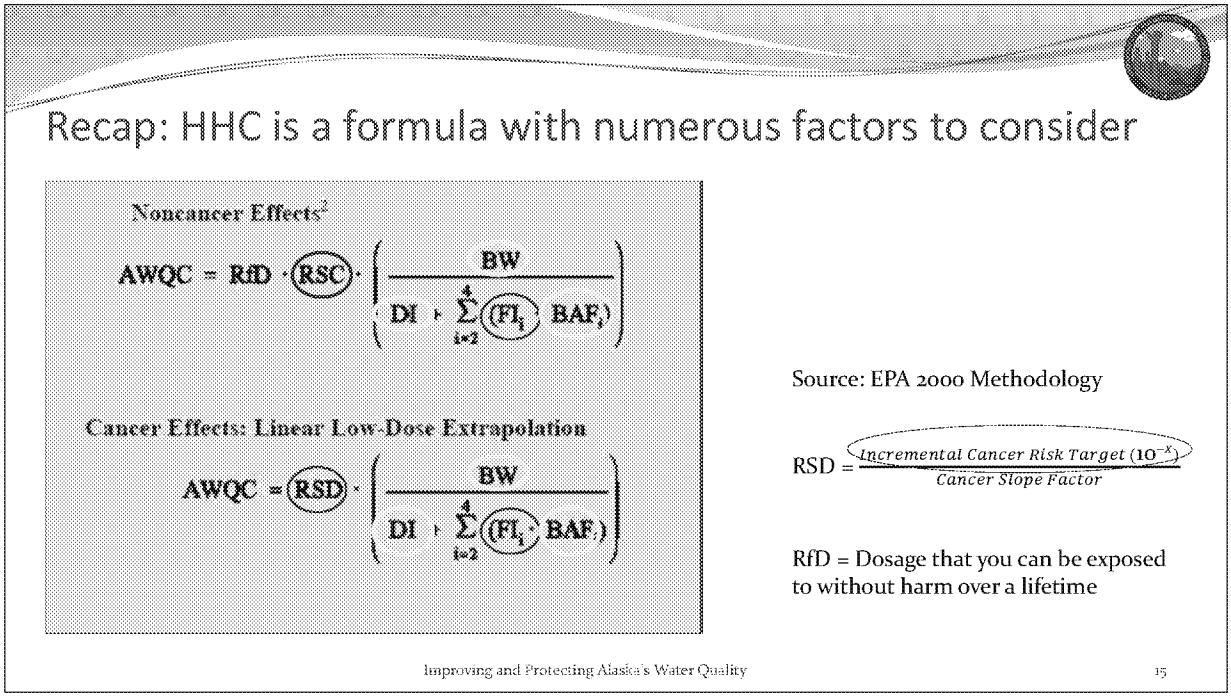
Biomagnification is the increase in the concentration of contaminates in the food chain- higher amount of contaminates in a polar bear than in shrimp



Accounts for sources of exposures other than consumption of aquatic life
EXAMPLE: If you assume ~20% of your daily exposure to a toxic substance comes from sources OTHER than eating fish and drinking from a stream/lake, then 80% is available to use in calculating the HHC
RSC of 1 means that 100% of daily exposure is available for use in the criteria calculation

There's a fundamental concern that use of the Clean Water Act to regulate toxics is problematic. That said, its not our place to determine whether this is or isn't a good policy but rather to determine whether there is information that would allow for certain criteria to be adjusted depending on available information on source contribution (e.g., adjust upward based on source information like Florida has done)

DEC plans to hold an entire follow-up webinar on this issue



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Essentially we are making decisions about the degree of risk we are willing to live with using science and policy as our sidebars.

Red Denotes those exposure issues that DEC will be actively researching and making a determination on (science and risk management decisions)
Yellow are those exposure issues that do not appear to be controversial policy decisions

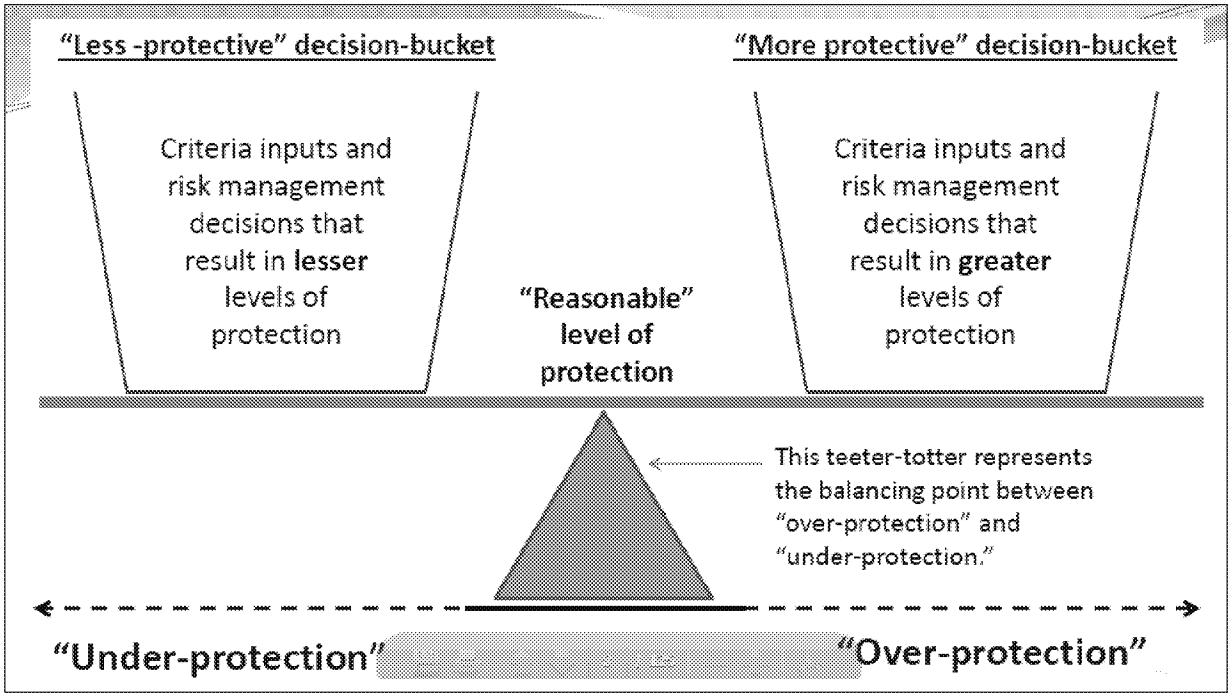

Image developed by Washington Ecology- http://www.ecy.wa.gov/programs/wq/swqs/PolicyForum6Presentation.pdf#page=21

Terms over and under protected are very subjective- opinions vary widely amongst interest groups

For HHC, acceptable levels of protection are somewhat defined by EPA guidance but policy and risk management choices will play a huge role in setting the "appropriate" level of protection in regulation.